

Exhibit D

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ACR–SIR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF INFERIOR VENA CAVA (IVC) FILTER PLACEMENT FOR THE PREVENTION OF PULMONARY EMBOLISM

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology (SPR).

Pulmonary embolism (PE) continues to be a major cause of morbidity and mortality in the United States. Estimates of the incidence of nonfatal PE range from 400,000 to 630,000 cases per year, and 50,000 to 200,000 fatalities per year are directly attributable to PE [1-8].

Many devices have been developed for endoluminal caval interruption. Currently, several devices designed for permanent placement are commercially available in the United States. In addition to permanent inferior vena cava (IVC) filters, retrievable and convertible IVC filters are also available. The retrievable filters can be left in place as a permanent implant but also can be removed when the indication for filter placement resolves. (For detailed information regarding each of these filters, the reader is referred to several reviews [9-27].) Device selection is dependent on many factors, including, but not limited to, clinical indication, anatomy of the ilio caval veins and available venous access sites, device-specific outcomes data, magnetic resonance imaging (MRI) compatibility, ease of placement, and experience of the operator.

The IVC should be assessed with imaging prior to placement of a filter. The current preferred method is by vena cavography. Intravascular ultrasound (IVUS) has been utilized as an adjunct or primary tool for IVC assessment in certain situations. However, the use of IVUS is beyond the scope of this document [28-30]. The length and diameter of the IVC should be assessed, the location and number of renal veins determined, IVC anomalies defined (eg, duplication), and intrinsic IVC disease such as pre-existing thrombus or extrinsic compression should be assessed. If available, prior imaging studies (such as contrast-enhanced computed tomography [CT] or MRI of the abdomen and pelvis) should be reviewed to evaluate the anatomy of the IVC (size, patency, and anatomical variants) and to determine intrinsic IVC disease and extrinsic compression. The recommended location for filter placement for preventing PE from a lower extremity or pelvic venous source thromboembolism is the infrarenal IVC. It is a generally accepted belief that the apex or superior aspect of any filtration device should be at or immediately inferior to the level of the renal veins, according to the manufacturer's recommendations. In specific clinical circumstances other target locations, such as the suprarenal IVC, iliac veins, or both sides of a duplicated IVC, may be appropriate.

Although retrievable filters are often placed as permanent devices, the long-term safety and efficacy of these devices as a class have not been established. However, all retrievable convertible filters are approved for permanent placement. When a retrievable filter is placed, the patient should be clinically reassessed periodically to weigh the benefits of continued filtration (need for PE prophylaxis) against the associated risks (eg, recurrent deep venous thrombosis [DVT], IVC thrombosis, symptomatic penetration, or mechanical failure) and uncertainties (given limited data on long-term mechanical stability and integrity of some devices). The current recommendation is to consider removal of the IVC filter as soon as mechanical protection against PE is no longer needed [31]. Filters placed with the intent of subsequent retrieval may be left in place permanently for any of several reasons (eg, continuing need for filtration, thrombus on the filter, or inability to retrieve the filter). Data for the feasibility of filter retrieval vary widely among devices and centers.

These practice parameters are intended to be used in quality improvement programs to assess percutaneous interruption of the IVC to prevent PE. The most important aspects of care are 1) patient selection, 2) performing the procedure, and 3) monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

II. DEFINITIONS [32,33]

For the purpose of this practice parameter, the following definitions apply:

Permanent placement – deployment in those situations where lifelong mechanical protection against thromboembolic episodes is needed

Temporary placement – deployment in those situations where time-limited mechanical protection against thromboembolic episodes is needed

Procedural success – deployment of a filter in the intended location (target zone) such that the filter is judged suitable for mechanical protection against PE

Postfilter recurrent PE – PE occurring after filter placement and documented by pulmonary arteriography, cross-sectional imaging, significant change in ventilation-perfusion (V/Q) lung scan indicative of recurrent PE, surgical embolectomy, or autopsy

Postfilter thrombotic occlusion of the IVC – presence of an occluding thrombus in the filter and/or the IVC occurring after filter insertion and documented by ultrasound, CT, MRI, venography, or autopsy; this may be symptomatic or asymptomatic.

Filter penetration – penetration of the vein wall by a filter strut with transmural incorporation. For quality improvement reporting purposes, the definition of IVC penetration by a filter is filter strut or anchor devices extending >3 mm outside the wall of the IVC as demonstrated by CT, venography, or autopsy. Acute penetration occurring during placement of the filter is considered an insertion complication (see below).

Filter embolization – postdeployment movement of the filter or its components to a distant anatomic site completely out of the target zone

Filter movement – a change in filter position compared to its deployed position (either cranial or caudal) of >2 cm as documented by plain-film imaging, CT, or venography

Filter fracture – any loss of a filter's structural integrity (ie, breakage or separation) documented by imaging or autopsy

Insertion complication – malfunctions of the filter or deployment system such as incomplete filter opening, filter tilt >15° from the IVC axis, misplacement of filter outside the infrarenal IVC when the operator's intent is to place the filter in the infrarenal IVC (eg, when a portion of the filter is within one iliac vein), deploying the filter in the incorrect orientation (eg, upside down in the IVC), or prolapse of filter components. Filter malposition requiring surgical/endovascular removal is considered an insertion problem complication.

Access site thrombus – occlusive or nonocclusive thrombus developing at the venotomy site after filter insertion and documented by ultrasound or other imaging

Access site complications with clinical sequelae – arteriovenous fistula, hematoma, or bleeding requiring transfusion, hospitalization (either admission or extended stay), or further treatment

III. INDICATIONS [32-43]

Indications include, but are not limited to:

A. Therapeutic (Documented Thromboembolic Disease)

1. Patients with evidence of pulmonary embolus or DVT involving the IVC, iliac, or femoral-popliteal veins and 1 or more of the following:
 - a. A high risk of a complication from anticoagulation [34,38]
 - b. An absolute or relative contraindication to anticoagulation
 - c. Failure of anticoagulation [34]
 - i. Recurrent symptomatic PE despite adequate anticoagulant therapy
 - ii. Inability to achieve/maintain adequate anticoagulation
 - iii. Propagation/progression of DVT on therapeutic anticoagulation
2. Perioperative patients with a history of prior venous thromboembolism (VTE) for whom anticoagulation must be interrupted [34]
3. Massive PE postsurgical or endovascular thrombolysis/thrombectomy with residual deep venous thrombus [44]
4. Severe cardiopulmonary disease and DVT (eg, cor pulmonale with pulmonary hypertension) [44]

B. Prophylactic (No Current Thromboembolic Disease)

Because the risk-benefit ratio for use of IVC filters for primary PE prophylaxis in patients without a documented DVT has not been clearly characterized, physicians who place them for this indication are strongly encouraged to monitor the actual outcomes achieved and adjust patient selection practices accordingly. All filters placed for primary PE prophylaxis should be of retrievable type, with a defined follow-up plan to subsequently retrieve them unless clinically contraindicated for retrieval [38].

1. Patients at high risk of DVT/PE but cannot receive prophylactic anticoagulation due to underlying risk of bleeding. The risk of bleeding may be related to underlying clinical disease (cirrhosis, active gastrointestinal ulcer, systemic coagulopathy, etc). Such conditions include, but not limited to:
 - a. Severe craniospinal injury resulting in prolonged immobilization or plegic limbs [40]
 - b. Pelvic/long-bone fractures [40]
 - c. Intra-abdominal mass/hemorrhage compressing pelvic veins or the IVC [40]

C. Suprarenal Filter Placement [42]

Suprarenal caval filter placement may be considered when any of the following situations exist in addition to the indications listed above:

1. Presence of IVC thrombus precluding placement of a filter in the infrarenal IVC
2. Filter placement during pregnancy
3. Thrombus extending above a previously placed infrarenal filter
4. Gonadal vein thrombosis
5. Anatomic variants: duplication of the IVC, short length of infrarenal IVC
6. Significant extrinsic compression of the infrarenal IVC
7. Intrinsic narrowing of the infrarenal IVC
8. Patients with an intra-abdominal or pelvic mass who will undergo surgery and in whom operative IVC mobilization is contemplated

D. Filters Placed for Temporary Use and Possible Future Retrieval

The indications for filter placement remain the same as described above, except that the mechanical protection for PE is required for short term due to transient inability to anticoagulate a patient [38].

The use of retrievable filters should also be considered in pediatric and young adult patients since the long-term effects and durability of permanent IVC filters are not precisely known. Currently, there are no filters specifically designed for use in children. The safety of vena cava filters in children is unknown [45,46].

The threshold for these indications is 95%. When <95% of procedures are performed for these indications, the process of patient selection should be reviewed according to institutional policy.

IV. RELATIVE CONTRAINDICATIONS

A. Uncorrectable Severe Coagulopathy

B. Bacteremia or Untreated Infection

Clinical judgment should be applied in these situations, weighing the theoretical risk of implant infection versus the risk of PE.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications:

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of IVC filter procedures to demonstrate competency as attested by the supervising physician(s).
or
2. Completion of a residency program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) and has performed (with supervision) a sufficient number of IVC filter procedures to demonstrate competency as attested by the supervising physician(s).
or
3. Physicians whose residency or fellowship training did not include the above may still be considered qualified to perform IVC filter procedures provided that the following can be demonstrated:

The physician must have at least 2 years of endovascular procedural experience, during which the physician was supervised and during which the physician performed at least 25 percutaneous vascular procedures, including a minimum of 5 IVC filter placement procedures with outcomes within the quality improvement thresholds of this document.

4. Physicians meeting any of the qualifications in 1, 2, and 3 above must also have written substantiation that they are familiar with all of the following:
 - a. Indications and contraindications for the procedure

- b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and potential complications
- c. Where applicable, pharmacology of moderate-sedation medications and recognition and treatment of adverse reactions and complications
- d. Appropriate use and operation of fluoroscopic and radiographic equipment, mechanical injectors, digital image capture devices, and electronic imaging systems
- e. Where applicable, principles of radiation protection, hazards of radiation, and radiation monitoring requirements as they apply to both patients and personnel
- f. Where applicable, pharmacology of contrast agents and recognition and treatment of potential adverse reactions
- g. Percutaneous needle and catheter introduction techniques
- h. Technical aspects of performing the procedure, including the use of alternative catheter and guidewire systems, contrast materials, and filming sequences
- i. Anatomy, physiology, and pathophysiology of peripheral and central venous vasculature
- j. Postprocedure patient management, especially recognition and initial management of complications
- k. Postprocedure management of puncture sites
- l. Principles, operation, and imaging findings of vascular ultrasound, where applicable

The written substantiation should come from the chief of interventional radiology, the chair of the department of radiology, or his or her designee at the institution in which the physician will be providing these services. Substantiation could also come from a prior institution in which the physician provided the services, but only at the discretion of the chair of the department of radiology or his or her designee who solicits the additional input.

Maintenance of Competence

Physicians must perform a sufficient number of filter placement procedures to maintain their skills, with acceptable success and complication rates as presented in this document (see section X). Continued competence should depend on participation in a quality improvement program that monitors these rates.

Continuing Medical Education

The physician's continuing education should be in accordance with the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [47].

B. Qualified Medical Physicist

For qualifications of the Qualified Medical Physicist, see the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment](#) and the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic Equipment](#).

C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled "Radiologist Assistant: Roles and Responsibilities" and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006)

D. Radiologic Technologist

1. The technologist, together with the physician and nursing personnel, should be responsible for patient comfort and safety. The technologist should be able to prepare and position² the patient for the filter placement procedure and, together with the nurse, monitor the patient during the procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. If intravenous contrast material is to be administered, qualifications for technologists performing intravenous injection should be in compliance with current ACR policy³ and existing operating procedures or manuals at the facility. The technologist should also perform the regular quality control testing of the equipment under the supervision of the physicist.
2. Technologists should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license with documented training and experience in the imaging modality used for the imaging-guided procedure.

E. Nursing Services

Nursing services, when deemed appropriate by the performing physician, are an integral part of the team for preprocedure and postprocedure patient management and education and are recommended in monitoring the patient during the procedure.

VI. SPECIFICATIONS OF THE EXAMINATION

There are several technical requirements to ensure safe and successful filter placement procedures. These include adequate angiographic equipment and institutional facilities, physiologic monitoring equipment, and support personnel.

A. Equipment and Facilities for Filter Placement

The following are considered the minimum equipment requirements for performing vena cavagrams and filter placement. In planning facilities for IVC placement, equipment and facilities more advanced than those outlined below may be desired to produce higher-quality studies with reduced risk and time of study. At a minimum, the facility should include the following:

1. A high-resolution image receptor, preferably with a 28-cm to 40-cm field of view, and an imaging chain with either standard angiographic filming capabilities including serial 14-inch film changers or (preferably) a digital imaging system with a minimum 1024-image matrix. Digital angiographic systems are preferred as they allow for reduced volumes of contrast material and reduced examination times. Images are acquired and stored either on conventional film or digitally on computerized storage media. Imaging and image recording must be consistent with the “as low as reasonably achievable” (ALARA) radiation safety guidelines. The use of cineradiography or small-field mobile image intensifiers is inappropriate for the routine recording of the vena cavagram and IVC placement because these methods

²The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available*. There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (ACR Resolution 26, 1987 – revised in 2007, Resolution 12-m)

*For the purposes of this guideline, “personally and immediately available” is defined in manner of the “personal supervision” provision of CMS—a physician must be in attendance in the room during the performance of the procedure. Program Memorandum Carriers, DHHS, HCFA, Transmittal B-01-28, April 19, 2001.

³See the [ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media](#).

cause an unacceptably high patient and operator radiation dose. Use of last image hold and pulsed fluoroscopy are recommended for dose reduction.

2. Adequate angiographic supplies such as catheters, guidewires, needles, and introducer sheaths
3. An angiographic injector capable of varying injection volumes and rates with appropriate safety mechanisms to prevent overinjection
4. An angiography suite that is large enough to allow easy transfer of the patient from the bed to the table and allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally there should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions.
5. An area within the institution appropriate for patient preparation prior to the procedure and for observation of patients after the procedure. This might be within the radiology department, a short-stay unit, a routine nursing unit, or a postanesthesia care unit. At this location, there should be personnel to provide care as outlined below (Patient Care), and there should be immediate access to emergency resuscitation equipment.

B. Physiologic Monitoring and Resuscitation Equipment

1. Equipment should be present in the procedure suite to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. For facilities using moderate sedation, a pulse oximeter monitor should be available (see the [ACR–SIR Practice Parameter for Sedation/Analgesia](#) [48]).
2. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be maintained and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

C. Support Personnel

1. Radiologic technologists properly trained in the use of the angiographic equipment should assist in performing and imaging the procedure. They should demonstrate appropriate knowledge of patient positioning; angiographic image recording; angiographic contrast injectors; angiographic supplies, including IVC filters; and the physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. The technologist should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.
2. If the patient does not receive sedation for the procedure, one of the staff assisting the procedure should be assigned to periodically assess the patient's status. In cases where moderate sedation is used in adults or children or the patient is critically ill, an experienced, licensed provider should be present, whose primary responsibility is monitoring the patient's vital signs, sedation state, and level of comfort or pain. This person should maintain a record of the patient's vital signs, the time and dose of medications given, and other pertinent information (see the [ACR–SIR Practice Parameter for Sedation/Analgesia](#) [48]).

D. Acute Care Support

Although surgical or other emergency treatment is needed infrequently for serious complications after filter placement procedures, there should be prompt access to surgical and interventional equipment and to specialists

familiar with the management of patients with complications in the unlikely event of a life-threatening complication.

E. Patient Care

For additional information see the [ACR–SIR–SNIS–SPR Practice Parameter for Interventional Clinical Practice and Management](#) [49].

1. Preprocedure care

For elective filter placement, the following should be documented:

- a. Clinically significant history, including indications for the procedure
- b. Clinically significant physical or diagnostic examination findings, including clinical or medical conditions that may necessitate specific care, such as preprocedure antibiotics and other measures
- c. Clinically indicated laboratory evaluation including, but not limited to, coagulation factors, creatinine, white blood cell count, and previously obtained cultures
- d. Preprocedure documentation should conform to the requirements of the [ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures](#) [50]

Informed consent must be in compliance with all state laws and the [ACR–SIR Practice Parameter on Informed Consent for Image-Guided Procedures](#) [51].

For emergency procedures, a note should be written summarizing the indication for the study, the pertinent history and physical findings, if available, and the proposed procedure.

2. Procedural care

- a. Adherence to the Joint Commission’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in nonoperating room settings, including bedside procedures. The organization should have processes and systems in place for reconciling differences in staff responses during the “time-out.”
- b. All patients should have cardiac monitoring continuously during the procedure, with intermittent blood pressure monitoring. A record of vital signs should be maintained.
- c. All patients should have intravenous access for the administration of fluids and medications as needed.
- d. If the patient is to receive sedation for the procedure, pulse oximetry should be used. A registered nurse or other appropriately trained personnel should be present, and his/her primary responsibility should be to monitor the patient. A record should be kept of medication doses and times of administration. See the [ACR–SIR Practice Parameter for Sedation/Analgesia](#) [48].

3. Postprocedure care

- a. All patients should be at bed rest and observed in the initial postprocedure period. The length of this period of bed rest will depend on the site and size of the venotomy and the patient’s medical condition.
- b. During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site.
- c. Initial ambulation of the patient must be carefully supervised. The puncture site stability and independent patient function and mobility must be assured.
- d. The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If moderate sedation was administered prior to and during the procedure, complete recovery from sedation must be documented. The physician or designee should be available for continuing care during hospitalization and after discharge. The designee may be another physician or a nurse. See the [ACR–SIR Practice Parameter for Sedation/Analgesia](#) [48].

- e. Patients in whom a retrievable IVC filter is implanted should undergo clinical reassessment for the appropriateness and timing of filter removal during the first 3 to 6 months after placement (depending on the device-specific time window for retrieval). The operating physician should participate in this clinical assessment.

F. Selection Criteria for Short-Term Observation

The duration of postprocedure observation must be individualized. IVC filter placement can be performed on some patients with a short period of postprocedure observation (<6 hours) prior to discharge to home; others require overnight care. Short-term observation should only be considered when all the following conditions can be met:

1. Those patients capable of independent ambulation prior to the procedure demonstrate stable independent ambulation after the procedure. Nonambulatory patients have adequate assistance after discharge to provide care as needed.
2. The patient is capable of following instructions and detecting changes in symptomatology. Alternatively, patients with impaired mental or neurologic status should have adequate assistance after discharge to provide care as needed.
3. The patient is provided with instructions on how to recognize potential complications and how to obtain medical assistance in the event of such complications. A responsible adult is also provided with information regarding recognition of potential complications and is available to transport the patient and be in attendance during the initial night after discharge.
4. The patient is free of concurrent serious medical illness that might contribute to a significantly increased risk of complication.
5. The patient has recovered from the effects of the sedation.

G. Relative Contraindications to Short-Term Observation

Several factors must be considered when determining the length of postprocedure skilled nursing care. Some of the relative contraindications to short-term observation are listed below.

1. Patients with significant risk of contrast media–associated nephrotoxicity that might be prevented by hospitalization and intravenous hydration
2. Patients with coagulopathies or electrolyte abnormalities that require correction should be hospitalized until stable.
3. Insulin-dependent diabetics who have labile serum glucose levels in the periprocedural period should be hospitalized until stable.
4. Complications occurring during or after IVC filter placement, including large hematoma, anuria, and persistent nausea and vomiting, should prompt observation until symptoms resolve.
5. Patients who exhibit hemodynamic instability or significant dysrhythmia during or after the procedure should be hospitalized until stable.
6. Patients who live alone

7. Patients with concurrent serious medical illness that might contribute to a significantly increased risk of complication should be hospitalized until stable.
8. Patients with impaired mental or neurologic status who do not have adequate assistance to provide care as needed should be hospitalized until appropriate assistance is available or no longer required.

The decision for short-term or longer-term postprocedure observation must be individualized, and a patient's care may vary from the above criteria for sound clinical reasons. The decision in each case must be made by the physician who performed the procedure and the referring physician after review of all pertinent data.

VII. DOCUMENTATION

Reporting should be in accordance with the [ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures](#) [50].

VIII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, “as low as reasonably achievable” (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels)

http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf.

Nationally developed guidelines, such as the ACR [Appropriateness Criteria](#)[®], should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently[®] for children (www.imagegently.org) and Image Wisely[®] for adults (www.imagewisely.org) websites. These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends. (ACR Resolution 17, adopted in 2006 – revised in 2009, 2013, Resolution 52).

IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education, appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<http://www.acr.org/guidelines>).

These data should be utilized in conjunction with the thresholds described in section X below to assess filter placement procedural efficacy and complication rates and to trigger institutional review when these thresholds are exceeded.

X. QUALITY IMPROVEMENT

A. Success Rates and Thresholds

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus, indicator thresholds may be used to assess the efficacy of ongoing improvement programs.

For the purpose of these practice parameters, a threshold is a specific level of an indicator that should prompt a review. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a minimum threshold or when complication rates exceed a maximum threshold, a review should be performed to determine causes and to implement changes, if necessary.

Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Thus, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values to meet its own quality improvement program needs.

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight) (see Appendix A). The complication rates and thresholds below refer to major complications.

It is expected that the technical success for percutaneously placed IVC filters will be 97% or better in experienced hands. Therefore, the proposed threshold for review of technical failures should be 3%.

B. Complication Rates and Thresholds

1. Complications

Each currently available filter has been extensively studied as part of the FDA approval process. Few comparative studies have been completed evaluating all filters in one project, and those that have done so have been retrospective analyses. Complication rates are highly variable depending on the filter being studied. For simplicity, these practice parameters do not suggest threshold rates for each individual filter; rather, filtration devices are considered as a group.

TABLE 1

Complications	Reported Rates (%)	Threshold (%)
Death [52]	0.12	< 1
Filter embolization [9,32,45,46,53-65]	0.1	1
Deployment outside target area [34,66,67]	1-9	<1%
Access site thrombosis occlusive [68,69]	3-10	3

Published rates for individual types of complications are highly dependent on patient selection and are in some cases based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient volume (eg, early in a quality improvement program).

2. Other trackable events

Because an IVC filter may be implanted as a permanent device (if not retrieved) and can be used in relatively young patients, several other trackable parameters are appropriate to record in a quality improvement program. The following events may or may not be clinically significant in a particular patient. For this reason, thresholds for these events are not included in this document.

TABLE II

Other Trackable Events	Reported Rates (%)
IVC penetration* [7,10,12,13,15,16,21,32-39,42,51,52,58,59,61,63,65,67-76]	0-100
Migration of filter/filter components* [10,11,13,16,18,19,21,24,31,32,34,36,40-43,45,52,55,56,63,65,67,70-85]	0-25
Filter fracture [9-17,21,32,34,37,39,51,53,54,58,60-62,66,71-74,76,78,80,81,83-86]	0-50
Recurrent PE [32,71,72,78,82]	0.5-6
Access site thrombus – all types [52,68,83,84,86]	0-25
IVC occlusion [12,14,15,20,26,27,30,32,34,36,41,43-46,51,56-58,61,69-77,79,82,85,87,88]	2-65
Insertion problems [32,52,61,71,72,78,79,82,84,87,88]	5-23
Other complications [2,75]	1-15

The data in the table represents reported outcomes from various publications and not the SIR standard for complications.

* The rate of clinically significant penetration is not precisely known [85].

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Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology, in collaboration with the SIR and the SPR.

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APPENDIX A

**Society of Interventional Radiology
Standards of Practice Committee
Classification of Complications by Outcome**

Minor Complications

- A. No therapy, no consequence
- B. Nominal therapy, no consequence; includes overnight admission for observation only

Major Complications

- C. Require therapy, minor hospitalization (<48 hours)
- D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)
- E. Permanent adverse sequelae
- F. Death

*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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